Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy

CENTENE® Corporation

Clinical Policy: Potassium Citrate/Potassium Bicarbonate (ADV7013)

Reference Number: CP.PMN.310
Effective Date: FDA Approval Date
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Potassium citrate/potassium bicarbonate (ADV7013®/™) is a combination alkalinizing agent.

FDA Approved Indication(s) [Pending]

ADV7013 is indicated for the treatment of distal renal tubular acidosis (dRTA).

Limitation(s) of use: [XXX]

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that ADV7013 is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Distal Renal Tubular Acidosis (must meet all)**:**

1. Diagnosis of dRTA;*
2. Prescribed by or in consultation with a nephrologist;*
3. Age ≥ 6 months;*
4. Failure to normalize serum bicarbonate concentrations to ≥ 22 mEq/L with both of the following (a and b, see *Appendix B*), unless clinically significant adverse effects are experienced or both are contraindicated*:*
   **For Illinois HIM requests, the step therapy above does not apply as of 1/1/2026 per IL HB 5395*
   a. A citrate-based alkali therapy (e.g., potassium citrate or sodium citrate);
   b. A bicarbonate-based alkali therapy (e.g., potassium bicarbonate or sodium bicarbonate);
5. Estimated glomerular filtration rate (eGFR) ≥ 45 mL/min/1.73 m^2;*
6. Documentation of member's current body weight (in kg);
7. Dose does not exceed both of the following (a and b): *
   a. 10 mEq/kg/day;
   b. 336 mEq/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Distal Renal Tubular Acidosis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Member is responding positively to therapy as evidenced by an increase in serum bicarbonate concentration levels;*
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):*
   a. 10 mEq/kg/day;
   b. 336 mEq/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
dRTA: distal renal tubular acidosis
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
potassium citrate (Urocit-K®)	Initial dosing: • Mild-moderate hypocitraturia (< 150 mg/day): 15 mEq PO BID or 10 mEq PO TID • Severe hypocitraturia (> 150 mg/day): 30 mEq PO BID or 20 mEq PO TID Dose range: 5 to 100 mEq/day	Based on clinical response
potassium citrate-citric acid (Polycitra K, Cytra-K)	• Adults: 100 to 200 mEq/day PO divided every 6 to 8 hours or 20 to 60 mEq PO every 6 to 8 hours • Pediatrics: 1 to 3 mEq/kg/day PO divided every 6 to 8 hours or 10 to 30 mEq PO every 6 to 8 hours	Based on clinical response
potassium bicarbonate-citrate acid (Effer-K®)	1 to 8 mEq/kg/day PO in 2 to 3 divided doses; Adjust dose as needed based on clinical response (e.g., serum bicarbonate concentrations)	Based on clinical response

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sodium citrate-citric acid (Cytra-2, Oracit)	• Adults: 100 to 200 mEq/day PO divided every 6 to 8 hours or 20 to 60 mEq PO every 6 to 8 hours • Pediatrics: 1 to 3 mEq/kg/day PO divided every 6 to 8 hours or 5 to 15 mEq PO every 6 to 8 hours	Based on clinical response
sodium bicarbonate	• Adults: 1 to 3 mEq/kg/day PO in 2 to 3 divided doses • Pediatrics: 2 to 4 mEq/kg/day PO in 2 to 3 divided dsoes • Neonates/infants: 1 to 8 mEq/kg/day PO in 2 to 3 divided doses	Based on clinical response

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): pending
- Boxed warning(s): pending

General Information

- Citrate-based alkali therapy refers to alkali citrate salts (such as potassium citrate or sodium citrate), which are used to treat metabolic acidosis and prevent kidney stones by raising urine pH. While citric acid is bonded with hydrogen ions, making it acidic, and does not provide a significant alkali load on its own. Citric acid is a versatile pharmaceutical excipient that is used to enhance drug stability, taste, and delivery.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
dRTA *	The starting daily dose is based on age and weight and incrementally titrated based on plasma bicarbonate levels: Total daily dose given PO in two divided doses*	10 mEq/kg/day or 336 mEq/day, whichever less*

VI. Product Availability [Pending]

Delayed-release oral granule sachets:

- 8 mEq (282 mg potassium citrate-527 mg of potassium bicarbonate)*
- 24 mEq (847 mg of potassium citrate-1,582 mg of potassium bicarbonate)*

VII. References

1. Bertholet-Thomas A, Guittet C, Manso-Silvan MA, et al. Efficacy and safety of an innovative prolonged-release combination drug in patients with distal renal tubular acidosis: an open-label comparative trial versus standard of care treatments. Pediatric Nephrology. 2021; 36:83-91.

2. Bertholet-Thomas A, Guittet C, Manso-Silvan MA, et al. Safety, efficacy, and acceptability of ADV7103 during 24 months of treatment: an open-label study in pediatric and adult patients with distal renal tubular acidosis. Pediatric Nephrology. 2021; 36:1765-1774.
3. Bertholet-Thomas A, Del Mul A, Bernardor J, et al. 6-year treatment follow-up with an extended-release alkaline formulation (Sibnayal®) in primary distal renal tubular acidosis. Orphanet Journal of Rare Diseases. 2025;20(431):1-13.
4. Lopez-Garcia SC, Emma F, Walsh SB, et al. Treatment and long-term outcome in primary distal tubular acidosis. Nephrol Dial Transplant. 2019;34:981-991.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	05.19.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.